

REMARKS

Claims 1-31 are pending. Claims 1-31 have been subject to a restriction requirement under 35 U.S.C. § 121 to a single invention as identified by the groups that follow:

- I. Claims 1-6, drawn to a method of identifying compounds that modulate mammalian histamine H4 receptor activity, said compound being either an inhibitor, an activator, an antagonist, an agonist or an inverse agonist, said method comprising measuring the effect of the compound on protein function or ability to bind the ligand by combining a test compound with a mammalian histamine H4 receptor and a known histamine receptor H4 ligand, classified in Class 435, subclass 7.1.
- II. Claims 7-9, 12, 14, 16 and 18-23, drawn to a compound and pharmaceutical composition thereof, comprising either an inhibitor, an activator, an antagonist, an agonist or an inverse agonist of a mammalian histamine H4 receptor, classified in Class 536, subclass 6.2 and Class 514, subclass 740.
- III. Claims 10 and 11, drawn to a monospecific antibody that reacts with a mammalian histamine H4 receptor protein, wherein said antibody either blocks histamine binding or activation, of the mammalian histamine H4 receptor protein, and wherein the antibody either modulates mast cell chemotaxis or basophil chemotaxis, classified in Class 530, subclass 388.1.
- IV. Claims 13, 15, 17 and 24-29, drawn to a method for modulating asthma or an allergic response or a disease or condition mediated by one or the other, said method comprising administration of a pharmaceutical composition comprising a compound that is either an inhibitor, an activator, an antagonist, an agonist or an inverse agonist of a mammalian histamine H4 receptor, classified in Class 514, subclass 740.
- V. Claim 30, drawn to a method of identifying compounds that modulate mammalian histamine H4 receptor activity, said compound being either an inhibitor, an activator, an antagonist, an agonist or an inverse agonist, and said method comprising measuring mast cell migration or number in response to placing mast cells in proximity to histamine in the presence or absence of a test compound, classified in Class 435, subclass 7.1.

VI. Claim 31, drawn to a method of determining if a histamine H4 receptor modulating compound modulates sub-epithelial accumulation of mast cells in a mammalian trachea in response to exposure to histamine or an allergen, said compound being either an inhibitor, an activator, an antagonist, an agonist or an inverse agonist, and said method comprising measuring sub-epithelial mast cell accumulation in said trachea in the presence or absence of the compound in response to placing mast cells in proximity to histamine in the presence or absence of the said compound by exposing a mammal to an aerosol comprising histamine or an allergen, classified in Class 435, subclass 7.2.

According to MPEP § 803, there are two criteria for a proper requirement for restriction between patentably distinct inventions:

- (A) The inventions must be independent (see MPEP § 802.01, § 806.04, § 808.01) or distinct as claimed (see MPEP § 806.05-§ 806.05(i)); and
- (B) There must be a serious burden on the examiner if restriction is required (see MPEP § 803.02, § 806.04(a) to § 806.04(i), § 808.01(a), and § 808.02).

M.P.E.P. § 803.02 further states that if the members of a Markush group are sufficiently few in number or so closely related that a search and examination of the entire claim can be made without serious burden, all members must be examined on the merits. Furthermore, it is improper for the U.S. Patent and Trademark Office to refuse to examine that which applicants regard as their invention, unless the subject matter in a claim lacks unity of invention. See M.P.E.P. § 803.02, citing *In re Harnisch*, 631 F.2d 716, 206 U.S.P.Q. 300 (CCPA 1980).

Applicants elected Group V, claim 30, without traverse for examination on the merits. Applicants elect Group V without traverse insofar as the groups are directed to patentably distinct inventions. However, the restriction requirement is traversed to the extent that it requires election of a subgenus within the scope of claim 30 thus restricting the recited method of identifying compounds to one of the following types of compounds: inhibitor, activator, antagonist, agonist, or inverse agonist. Not only has the examiner failed to show that each of the subgeneric methods would fall within a different search class such that the search would be unduly burdensome, but the examiner has also failed to recognize that in performing the claimed method for drug discovery the property of the compound being tested

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is typically not known and therefore it is unreasonable to restrict the compound to one of the noted types. Therefore applicants respectfully request that the method of identifying compounds that modulate mammalian H4 receptor utilizing compounds of various subgenera be rejoined.

However, to be fully responsive to the restriction requirement, applicants elect Group V, claim 30, without traverse, and a compound group, antagonist, with traverse.

Applicants respectfully request prompt examination on the merits of the elected invention. If the Examiner believes that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided. Favorable consideration and an early notice of allowance are respectfully requested.

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/Phillip A. Singer/
Phillip A. Singer
Registration No.: 40,176

Woodcock Washburn LLP
One Liberty Place - 46th Floor
Philadelphia PA 19103
Telephone: (215) 568-3100
Facsimile: (215) 568-3439